

AMENDED IN ASSEMBLY AUGUST 30, 2001

AMENDED IN ASSEMBLY AUGUST 28, 2001

AMENDED IN ASSEMBLY AUGUST 20, 2001

AMENDED IN ASSEMBLY JULY 19, 2001

SENATE BILL

No. 293

**Introduced by ~~Senator Torlakson~~ *Senators Torlakson and
Figueroa***

February 16, 2001

An act to amend Section 4123 of, and to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. Pharmacies: injectable sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state. Existing law regulates controlled substances, dangerous drugs, and dangerous devices.

This bill would create new positions within the California State Pharmacy Board in order to carry out the provisions of the bill. The bill would appropriate \$580,000 from the Pharmacy Board Contingent Fund for purposes of the bill.

This bill would authorize the board, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring, ~~among other things,~~ the

pharmacy to refrain from ~~any activity that posed~~ *compounding injectable sterile drug products if that activity poses* an immediate threat to the public health or safety. The bill would implement quality assurance methods regarding the compounding of injectable sterile drug products. The bill would require the board to adopt necessary regulations regarding injectable sterile drug products. The bill would require specified pharmacies to obtain a license from the board in order to prepare injectable sterile drug products. *The bill would provide that the reconstitution of a sterile powder would not require a license if specified conditions are met.* By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

This bill would provide that a violation of the bill or regulations adopted pursuant to it would be subject to a fine of up to \$2,500. These fines would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning injectable sterile drug products, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ²/₃. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature hereby establishes five
2 positions in the California State Board of Pharmacy to implement
3 the provisions of this act. Those positions shall be apportioned as
4 follows: one supervising pharmacy inspector, two pharmacy
5 inspectors, one management services technician, and one office
6 technician.

7 The sum of five hundred eighty thousand dollars (\$580,000) is
8 hereby appropriated from the Pharmacy Board Contingent Fund
9 to the California State Board of Pharmacy for the costs associated



1 with the implementation of this act, including, but not limited to,
2 the salaries and benefits of the employees described in this section.

3 SEC. 2. Section 4123 of the Business and Professions Code
4 is amended to read:

5 4123. Any pharmacy that contracts to compound a sterile
6 drug product for delivery to another pharmacy, *a prescriber's*
7 *office, or a licensed health care facility* shall report that contractual
8 arrangement to the board. That information shall be reported by
9 the pharmacy performing the compounding services within 30
10 days of commencing that compounding.

11 SEC. 3. Article 7.5 (commencing with Section 4127) is added
12 to Chapter 9 of Division 2 of the Business and Professions Code,
13 to read:

14
15 Article 7.5. Injectable Sterile Drug Products

16
17 4127. The board shall adopt regulations establishing
18 standards for compounding *injectable* sterile drug products in a
19 pharmacy.

20 4127.1. (a) A pharmacy shall not compound injectable sterile
21 drug products in this state unless the pharmacy has obtained a
22 ~~license from the board pursuant to this section. A license shall be~~
23 ~~required for each location owned or operated by a specific person~~
24 ~~where injectable sterile drug products are compounded. The~~
25 ~~license from the board pursuant to this section. The~~ license shall
26 be renewed annually and is not transferable.

27 (b) A license to compound injectable sterile drug products may
28 only be issued for a location that is licensed as a pharmacy.
29 Furthermore, the license to compound injectable sterile drug
30 products may only be issued to the owner of the pharmacy license
31 at that location. A license to compound injectable sterile drug
32 products may not be issued until the location is inspected by the
33 board and found in compliance with this article and regulations
34 adopted by the board.

35 (c) A license to compound injectable sterile drug products may
36 not be renewed until the location has been inspected by the board
37 and found to be in compliance with this article and regulations
38 adopted by the board.

39 (d) Pharmacies operated by entities that are licensed by either
40 the board or the State Department of Health Services and that have

1 current accreditation from the Joint Commission on Accreditation
2 of Healthcare Organizations, or other private accreditation
3 agencies approved by the board, are exempt from the requirement
4 to obtain a license pursuant to this section.

5 (e) *The reconstitution of a sterile powder shall not require a*
6 *license pursuant to this section if all of the following are met:*

7 (1) *The sterile powder was obtained from a manufacturer.*

8 (2) *The drug is reconstituted for administration to a specific*
9 *patient by a health care professional licensed to administer drugs*
10 *by injection pursuant to this division.*

11 (3) *The reconstituted drug is immediately administered to the*
12 *patient.*

13 (f) This section shall become effective on the earlier of July 1,
14 2003, or the effective date of regulations adopted by the board
15 pursuant to Section 4127.

16 4127.2. (a) A nonresident pharmacy may not compound
17 injectable sterile drug products for shipment into the State of
18 California without a license issued by the board pursuant to this
19 section. A license shall be required for each location owned or
20 operated by a specific person or entity where injectable sterile drug
21 products are compounded. The license shall be renewed annually.

22 (b) A license to compound injectable sterile drug products may
23 only be issued for a location that is licensed as a nonresident
24 pharmacy. Furthermore, the license to compound injectable sterile
25 drug products may only be issued to the owner of the nonresident
26 pharmacy license at that location. A license to compound
27 injectable sterile drug products may not be issued or renewed until
28 the board receives the following from the nonresident pharmacy:

29 (1) A copy of an inspection report issued by the pharmacy's
30 licensing agency, or a report from a private accrediting agency
31 approved by the board, in the prior 12 months documenting the
32 pharmacy's compliance with board regulations regarding the
33 compounding of injectable sterile drug products.

34 (2) A copy of the nonresident pharmacy's proposed policies
35 and procedures for sterile compounding.

36 (c) ~~Pharmacies~~ *Nonresident pharmacies* operated by entities
37 that are licensed as a hospital, home health agency, or a skilled
38 nursing facility and have current accreditation from the Joint
39 Commission on Accreditation of Healthcare Organizations, or
40 other private accreditation agencies approved by the board, are

1 exempt from the requirement to obtain a license pursuant to this
2 section.

3 (d) This section shall become effective on the earlier of July 1,
4 2003, or the effective date of regulations adopted by the board
5 pursuant to Section 4127.

6 4127.3. (a) Whenever the board has a reasonable belief,
7 based on information obtained during an inspection or
8 investigation by the board, that ~~activity in~~ a pharmacy
9 compounding injectable sterile drug products poses an immediate
10 threat to the public health or safety, the executive officer of the
11 board may issue an order to the pharmacy to immediately cease
12 and desist from ~~that activity~~ *compounding injectable sterile drug*
13 *products*. The cease and desist order shall remain in effect for no
14 more than 30 days or the date of a hearing seeking an interim
15 suspension order, whichever is earlier.

16 (b) Whenever the board ~~orders the closure of a business~~ *issues*
17 *a cease and desist order* pursuant to subdivision (a), the board shall
18 immediately issue the owner a notice setting forth the acts or
19 omissions with which the owner is charged, specifying the
20 pertinent code section or sections.

21 (c) The order shall provide that the owner, within 15 days of
22 receipt of the notice, may request a hearing before the president of
23 the board to contest the ~~closure~~ *cease and desist* order.
24 Consideration of the owner's contest of the closure order shall
25 comply with the requirements of Section 11425.10 of the
26 Government Code. The hearing shall be held no later than five
27 days from the date the request of the owner is received by the
28 board. The president shall render a written decision within five
29 days of the hearing. In the absence of the president of the board,
30 the vice president of the board may conduct the hearing permitted
31 by this subdivision. Review of the decision of the president of the
32 board may be sought by the owner or person in possession or
33 control of the pharmacy pursuant to Section 1094.5 of the Code of
34 Civil Procedure.

35 (d) Failure to comply with a ~~closure~~ *cease and desist* order
36 issued pursuant to this section shall be unprofessional conduct.

37 4127.4. Notwithstanding any other provision of law, a
38 violation of this article, or regulations adopted pursuant thereto,
39 may subject the person or entity that committed the violation to a

1 fine of up to two thousand five hundred dollars (\$2,500) per
2 occurrence pursuant to a citation issued by the board.

3 4127.5. The fee for the issuance of a license, or renewal of a
4 license, to compound sterile drug products shall be five hundred
5 dollars (\$500) and may be increased to six hundred dollars (\$600).

6 SEC. 4. No reimbursement is required by this act pursuant to
7 Section 6 of Article XIII B of the California Constitution because
8 the only costs that may be incurred by a local agency or school
9 district will be incurred because this act creates a new crime or
10 infraction, eliminates a crime or infraction, or changes the penalty
11 for a crime or infraction, within the meaning of Section 17556 of
12 the Government Code, or changes the definition of a crime within
13 the meaning of Section 6 of Article XIII B of the California
14 Constitution.

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16 CORRECTIONS

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